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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/304,121	05/03/99	VOELLMY	R 870109.409

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EXAMINER

WINKLER, U

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/304,121

Applicant(s)

VOELLMY, RICHARD

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

The Amendment filed 15 September 2000 (Paper No. 11) in response to the Office Action of 13 March 2000 is acknowledged and has been entered. Claims 1-33 and 35 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Examiner Ulrike Winkler, Group Art Unit 1648**.

The rejection of claims 1 under 35 U.S.C. 102(b) as being anticipated by Moonen Chrit (WO 98/06864) is **maintained**. Applicant's arguments filed 15 September 2000 have been fully considered but they are not persuasive. The reference discloses a therapeutic gene under the control of a heat shock promoter which is interpreted to be one of the nucleic acid molecules, the endogenously present heat shock promoter and heat shock transcription factor are interpreted as being the other nucleic acid molecule. Therefore, the instant invention is anticipated by Moonen Chrit.

The rejection of claims 2, 7-26, 28-33 and 35 under 35 U.S.C. 102(b) as being anticipated by Moonen Chrit (WO 98/06864) is **withdrawn** due to Applicant's arguments.

The rejection of claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moonen Chrit (WO 98/06864) as applied to claims 1,2, 7-26, 28-33 above, and further in view of Zuo et al. (Molecular Cellular Biology 1995) is **withdrawn** due to Applicant's arguments.

New Grounds of Rejection:

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what transcription factor activates the third promoter: is it the first or second transcription factor?

Claims 1-33 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a molecular circuit that serves as a cascade of activation to eventually express the gene of interest. The specification prophetically mentions the potential universe of combinations that could be made yet does not disclose enough information in the form of working examples to guide the ordinary artisan to make a working combination that would be commensurate with the scope of the claims. Specific information regarding the promoters and transcription factors is required. The disclosure specifically teaches hsp70 stress promoter and a portion of the RNA leader sequence of the human *hsp70B* gene, operably linked to a gene, in this instance luciferase, and a *hsp70B*-mutated

HSF1 gene operably linked to a promoter. Therefore, the ordinary artisan would not recognize that applicant was in possession of all possible circuit combinations at the time the invention was made.

Claims 1-33 and 35 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a molecular circuit that utilizes the hsp70 stress promoter and a portion of the RNA leader sequence of the human *hsp70B* gene, operably linked to a gene, in this instance luciferase, and a *hsp70B*-mutated HSF1 gene operably linked to a promoter, does not reasonably provide enablement for all promoters and transcription factors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a molecular circuit that serves as a cascade of activation. The specification prophetically mentions the possible universe of combinations that could be made yet does not disclose enough information in the form of working examples to guide the ordinary artisan to make working combinations that would be commensurate with the scope of the claims. The disclosure specifically teaches hsp70 stress promoter and a portion of the RNA leader sequence of the human *hsp70B* gene, operably linked to a gene, in this instance luciferase, and a *hsp70B*-mutated HSF1 gene operably linked to a promoter. Presumably, the luciferase gene can be substituted with any gene of interest. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any molecular circuit that utilizes a stress inducible promoter which in turn activates a transcription factor, that activates a promoter that activates a gene of interest or the activates another transcription factor

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which activates a promoter and a gene of interest. In order to make such an activation cascade, detailed knowledge of the promoters and their activation sites and the transcription factor binding sites are needed. In addition it is essential that one knows how much of the promoter sequence is necessary to fulfill the requisite function. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to use any and all promoters and transcription factors. Therefore, in view of the speculative nature of the invention, the lack of predictability of the prior art, the breadth of the claims and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed. Therefore, there is lack of enablement for the entire scope of the invention.

Conclusion

No claims are allowed.

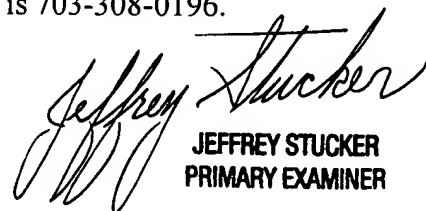
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.


JEFFREY STUCKER
PRIMARY EXAMINER